BK020033

SECTION II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitter Information:

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Date of Preparation: October 9, 2001
Reason for Submission: Extended indication for use (filtration up to 72 hours after platelet collection)

2. Device Name:

Trade/Proprietary Device Name: IMUGARD® III-PL Leukocyte Reduction Filter for preparation of leukocyte-reduced platelets

Common or Usual Device Name: Leukocyte Reduction Filter for Platelets

Classification Name: Microfilter, Blood Transfusion (21 CFR 880.5440)

3. Predicate Device:
The legally marketed device to which substantial equivalence is claimed is the IMUGARD® III-PL Leukocyte Reduction Filter for preparation of leukocyte-reduced platelets

4. Intended Use:
The IMUGARD® III-PL (Alternate designations PL-8L and IGIII-PL) is a leukocyte reduction filter for preparation of leukocyte-reduced platelets (For Platelet Concentrates or Single Donor Platelets).

The IGIII-PL filter is indicated for filtration up to 3 days after collection, of up to 8[1] units of platelet concentrates or filtration and storage of an equivalent therapeutic dose of single donor platelets. The IGIII-PL filter configuration is a Laboratory/ Blood Bank Use set. When used with a sterile tubing welder, permits subsequent storage of single donor platelets in a bag currently approved for apheresis 5-day platelets with no change to the original expiration date.

5. Device Description/Principle of Operation:
The IGIII-PL removes leukocytes from platelet concentrates and single donor platelets. The leukocyte-rich platelets flow in through the filter by gravity, the leukocytes are mostly mechanically trapped in narrow crevices or dimples of the polyurethane filter material and the leukocyte-reduced platelets flow out of the filter. It is designed for filtration of up to 8 units of platelet concentrates or filtration and storage of an equivalent therapeutic dose of single donor platelets. The IGIII-PL filter set configuration is for Laboratory/Blood Bank Use.

[1] Based on the use of 6-unit pools of RDPC derived from 500mL collections; these units approximated 8-10 unit pools derived from traditional 450mL collections.

The IGIII-PL for Laboratory/Blood Bank Use device consists of medical-grade polyvinyl chloride (PVC) blood bag tubing, a filter housing containing pre-filter and main filter, an air vent, Halkey-Roberts clamps, a plastic spike to connect to the unit to be filtered and an outlet port to connect to a filtrate storage container. The system may be used with a sterile connecting device to maintain a closed system.

6. Substantial Equivalence:
The IMUGARD® III-PL is substantially equivalent, in its intended use and function, to legally marketed filtration systems used for leukocyte reduction of platelets, specifically including the predicate device listed in Section 3 of this summary.

The IGIII-PL is constructed of the same materials, and is substantially equivalent to the predicate device in leukocyte reduction and platelet recovery as well as in its reliance on basic principles of filtration.

- **Intended Use**: The IMUGARD® III-PL is intended to leukocyte-reduce platelet concentrates and single donor platelets. This device (for filtration up to 3 days after collection) and the predicate device (for filtration up to 36 hours after collection) are designed for filtration of pooled platelet concentrates or filtration and storage of an equivalent therapeutic dose of single donor platelets.

- **Principles of Operation**: The IMUGARD® filter system operates by allowing leukocyte-rich platelets to flow through the filter by gravity.

- **Design and Materials**: The design and material construction of the IMUGARD® III-PL (PL-8L) has not changed.

  Studies have demonstrated the IGIII-PL for Laboratory/Blood Bank Use design has successful filtration up to 3 days after collection, of up to 8[2] units of platelet concentrates or filtration and storage of an equivalent therapeutic dose of single donor platelets. This same device (the predicate IGIII-PL for Laboratory/Blood Bank Use) was previously cleared for filtration up to 36 hours maximum after collection, of up to 8 units of platelet concentrates or filtration and storage of an equivalent therapeutic dose of single donor platelets.

7. Performance Testing:

Non-Clinical Testing:
Two in-vitro studies were conducted to demonstrate safe and effective performance of the IGIII-PL filter 3 days after collection. Both studies examined the leukocyte reduction performance in terms of residual white blood cells, flow time and platelet recovery, as well as in-vitro biochemical parameters indicative of platelet function. Both studies involved filtration of 6-unit pools of random donor platelet concentrates obtained from 500mL+ whole

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blood collections. These pools are equivalent to approximately 8-10 unit pools derived from 450mL collections. One site examined the leukocyte reduction performance of Baxter/Fenwal derived platelets (stored in PL732 platelet container), while the other site examined the leukocyte reduction performance of Terumo TERUFLEX derived platelets (stored in XT-612 platelet plus bag).

The results of both studies demonstrate effective leukocyte reduction with the use of the IGIII-PL filter system up to 3 days after collection, for a pool of up to 8[3] random donor platelet concentrates or an equivalent therapeutic dose of single donor platelets. The IGIII-PL filter provides levels of residual white blood cells, flow times and platelet recovery performance that support the claim of substantial equivalence to predicate devices. The biochemical indicators for platelet function are evidence of platelet viability post-filtration. These studies demonstrate safe and effective performance of the IMUGARD® III-PL filter.

In a separate in-vitro study conducted with apheresis platelet concentrates (APC) filtered on Expiration/Day 5 (96-120 hours after collection), platelet activation (assessed by CD62) values pre-filtration and post-filtration were comparable. These results demonstrate the safety of the polyurethane filter material of the IMUGARD® III-PL filter.

Clinical Testing:

Clinical studies were conducted at two sites under Institutional Review Board approval. These studies assessed in-vitro storage stability and in-vivo (radiolabeled platelets) recovery and survival of single random donor platelet concentrates filtered at Expiration/Day 5 (96-120 hours after collection). Comparisons were made between platelets filtered with the IGIII-PL system (Test) and non-filtered Controls. Platelets were derived from 500mL collections, CPD anticoagulated whole blood at one site and CPDA-1 anticoagulated whole blood at another.

In-Vivo platelet recovery and survival of single RDPC filtered at Expiration/Day 5 (96-120 hours) were measured. Average Recovery of filtered (test) platelets 24 hours after re-infusion was 52.8% (CPD) and 56.4% (CPDA-1). Mean Survival of filtered (test) platelets was 123.7 hours (CPD) and 184.9 hours (CPDA-1). No clinically significant differences between Test and non-filtered Controls were detected, demonstrating the safety and effectiveness of the IMUGARD® III-PL (PL-8L) filter.

[3] Based on the use of 6-unit pools of RDPC derived from 500mL collections; these units approximated 8-10 unit pools derived from traditional 450mL collections.